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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,794	07/15/2003	Jeff J. Staggs		1100
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JEFF J. STAGGS			EXAMINER	
9381 PRINCETON LN.,			WEDDINGTON, KEVIN E	
HIGHLAND RANCH, CO 80130				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/620,794	<b>Applicant(s)</b> STAGGS, JEFF J.
	<b>Examiner</b> KEVIN WEDDINGTON	<b>Art Unit</b> 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 April 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-22 is/are pending in the application.  
 4a) Of the above claim(s) 2 and 3 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1, 4-16 and 18-22 is/are rejected.  
 7) Claim(s) 17 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1668)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

The finality of the Office action dated February 2, 2009 is hereby removed so that new rejections can be made.

Claims 1-22 are presented for examination.

Applicant's amendment and response filed April 6, 2009 have been received and entered.

Claims 2 and 3 are considered to be cancelled since the applicant's amendment withdraws the claims before the examination of the application.

Accordingly, the rejection made under 35 USC 112, first paragraph (Written Description) as set forth in the previous Office action dated February 2, 2009 at pages 2-4 as applied to claims 1 and 7 is hereby withdrawn.

Accordingly, the rejection made under 35 USC 112, second paragraph as set forth in the previous Office action dated February 2, 2009 at pages 4-5 as applied to claims 1 and 4-22 is hereby withdrawn because the applicant deleted the indefinite phrase "or an equivalent".

Accordingly, the rejection made under 35 USC 102(b) as being anticipated by Yamaguchi et al., Kenkyu Kiyo-Tokyo Kasei Diagaku, Vol. 25, pp. 201-203 (1985) or Dorman et al., Journal of Applied Microbiology, Vol. 88, No. 2, pp. 308-316 (2000) as set forth in the previous Office action dated February 2, 2009 at pages 5-6 as applied to claim 4 is hereby withdrawn because of applicant's remarks.

***Claim Objections***

Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating an infectious disease caused by drug-resistant strain of bacteria such as *Staphylococcus aureus* with pepper, does not reasonably provide enablement for treating other infectious diseases caused by other types of drug-resistant strains of bacteria such as *Streptococcus* or *Clostridium difficile* with pepper. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided

- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of treating infectious diseases caused by drug-resistant strains of bacteria in a human or animal host comprising administering to the area of disease a suitable carrier containing an antibacterial agent obtainable from pepper.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

There It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of all type of drug-resistant strains of bacteria.

The amount of direction or guidance provided and the presence or absence of working examples

Applicant provides only one example of the treatment of drug-resistant strain bacteria such as *Staph aureus* on page 15, lines 13-31.

There are no examples showing other drug-resistant strains of bacteria such as *Streptococcus* or *Clostridium difficile* were eradicated with pepper.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to what other types of drug-resistant strains bacteria were eradicated with the administration of pepper. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claim 1 is not allowed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a written description rejection.

A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In particular, the specification as original filed fails to provide sufficient written bases of any of the agents demonstrating wherein possession of use of the broad term:

**bacterial infections and a pepper plant.** The mere fact that Applicant may have discovered one type of bacteria was eradicated with pepper is not sufficient to claim the entire genus of bacteria (gram-negative and gram-positive bacteria). The mere fact that

Applicant may have discovered one type of pepper plant is effective against *Staphylococcus* bacteria is not sufficient to claim the entire genus of pepper plants.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Claim 4 and 7 are not allowed.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 22 are rendered indefinite because the claims refer back to being "an equivalent", however, the term "or an equivalent" was deleted by the applicant.

Claims 21 and 22 do not have antecedent basis for being an equivalent.

Claims 21 and 22 are not allowed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Gal, "Capsicidin; a new compound with antibiotic activity from condiment paprika", Zeitschrift fuer Lebensmittel-Untersuchung und-Forschung (1964), 124(5), pp. 33-6 or Chen et al., "Antibacterial properties of some spice plants before and after heat treatment", Chinese Journal of Microbiology and Immunology, Vol. 18, No. 3, pp. 190-195 (Aug. 1985).

Gal teaches paprika, a pepper, is effective against several bacteria (see the abstract). Clearly, the reference anticipates applicant's invention of treating a bacterial infections caused by a bacteria with pepper (paprika is called red pepper).

Chen et al. teach sweet pepper, chili pepper, and brown pepper are effective against various bacteria such as *V. parahaemolyticus* and *P. vulgaris*.

Claim 4 is not allowed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gal, "Capsicidin; a new compound with antibiotic activity from condiment paprika", Zeitschrift fuer Lebensmittel-Untersuchung und-Forschung (1964), 124(5), pp. 33-6 or Chen et al., "Antibacterial properties of some spice plants before and after heat treatment", Chinese Journal of Microbiology and Immunology, Vol. 18, No. 3, pp. 190-195 (Aug. 1985).

Gal and Chen et al. were discussed above supra for the antibiotic and antibacterial properties of various peppers such as sweet pepper and chili pepper (also known as red pepper or capsicum pepper) and paprika.

The instant invention differs from the cited reference in that the cited reference does not teach the active agents, pepper, is effective to treat cellulitis, necrotizing fasciitis, and infectious disease caused by *Staphylococcus* bacteria. However, one skilled in the art would have assumed the instant active agent would be effective against types of bacteria (gram-negative and gram-positive) in the absence of evidence to the contrary.

Claims 7-16 and 18-20 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN WEDDINGTON whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm - 9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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